JAN - 8 2001 K003827

6 510(k) SUMMARY

December 8, 2000

This summary of Safety and Effectiveness is submitted in accordance with the requirements of 21 CFR 807.92

6.1 Establishment

Company	Bio-Plexus, Inc. 129 Reservoir Road Vernon, CT 06066
Registration Number	1224632
Contact	Paul A. Tenthorey Mgr., Regulatory Affairs and Quality Assurance Phone 860 870 6112 Fax 860 870 6118

6.2 Device

Trade name	*PUNCTUR-GUARD* ® Winged Set
Common Name	Winged Set
Class	II
Classification Name	Hypodermic Single Lumen Needle
Regulation	21 CFR 880.5570

6.3 Predicate Device

Trade Name	*PUNCTUR-GUARD* ® Winged Set
Company	Bio-Plexus, Inc.
510(k) Number	K961251
Marketing Approval	June 27, 1996

6.4 Description

The *PUNCTUR-GUARD*® Winged Set is a safety device for blood collection. It is supplied sterile and pyrogen-free, for single-use. It is compatible with industry-standard needle holders and blood collection tubes, or with syringes. Techniques for drawing blood are the same as with other Winged Sets.

Unlike similar Winged Sets on the market, the *PUNCTUR-GUARD*® Winged Set makes use of Bio-Plexus' safety technology: At the end of a blood draw, an internal cannula is advanced which renders the needle tip blunt before the needle is withdrawn from the patient. This blunt is activated and locked in place by rotating the third wing to the right.

6.5 Intended Use

The Intended Use for the *PUNCTUR-GUARD®* Winged Set is to collect blood.

6.6 Comparison to Predicate Device

The new *PUNCTUR-GUARD®* Winged Set is a redesigned device based on the predicate device. There are no changes in biological characteristics (sterile, pyrogen-free), use characteristics (single use), materials for invasive components, indications for use, and fundamental scientific technology (operating principle, mechanism of action, safety technology, activation mechanism for safety feature). The redesign included changes of sterilization method, sterilization site, dimensions, materials for non-invasive components, colorants, packaging, and production methods.

6.7 Performance Evaluation

The *PUNCTUR-GUARD®* Winged Set was subjected to a risk analysis (FMEA), and the Design Verification and Validation were performed to address the potential risks discussed. Categories included biological properties, device and packaging integrity, measurements of performance and safety parameters, clarity of User Instructions, and full functionality tests.

The test results showed that the *PUNCTUR-GUARD®* Winged Set will

- retain its integrity under conditions expected to occur in practical use,
- allow blood collection by the healthcare worker, using standard techniques,
- reliably activate the safety feature which renders the tip permanently blunt,
- assist in increasing the safety of the blood collection procedure by using established *PUNCTUR-GUARD®* technology.

6.8 Substantial Equivalence

Safety, effectiveness and user acceptability of the *PUNCTUR-GUARD®* Winged Set were demonstrated by bench testing and simulated use testing. Quantitative test values demonstrated the substantial equivalence of the *PUNCTUR-GUARD®* Winged Set to the predicate device.

Paul A. Tenthorey

Paul A. Tenthorey

Date: 12/8/00

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2001

Mr. Paul A. Tenthorey
Manager of Regulatory Affairs & Quality Assurance
Bio-Plexus, Incorporated
129 Reservoir Road
Vernon, Connecticut 06066-5705

Re: K003827
Trade Name: Punctur-Guard Winged Set for Blood Collection
Regulatory Class: II
Product Code: FMI
Dated: December 22, 2000
Received: December 26, 2000

Dear Mr. Tenthorey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8 Indications for Use Statement

510(k) Number K003827

Device Name *PUNCTUR-GUARD®* Winged Set

Indications for Use

The *PUNCTUR-GUARD®* Winged Set is a safety device for use in blood collection procedures. It is supplied sterile and pyrogen-free, for single use. The multi-sample luer adapter supplied with the device is compatible with industry-standard blood sample tubes and needle holders, or with syringes.

The *PUNCTUR-GUARD®* Winged Set should be used by health care workers experienced in phlebotomy. We recommend that the health care worker grasp the third wing and rotate it to the twelve o'clock position to achieve maximum control during insertion. Blood collection is performed in the same way as with other available devices.

At the end of a blood draw, before the needle is removed from the patient's arm, the *PUNCTUR-GUARD®* Winged Set is rendered blunt by rotating the third wing to lay flat on the right wing.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003827

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)